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United States Senate

WASHINGTON, DC 20510 - 3505

July 24, 2015

Ambassador Michael Froman
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20508

Dear Ambassador Froman:

The intellectual property standards in the Trans-Pacific Partnership (TPP) will have far-reaching effects on the health of individuals in TPP countries and global efforts to increase access to medicines, including many supported with U.S. taxpayer funds. I am concerned that the agreement will include protections for pharmaceutical companies at the expense of individuals' health and will hamstring the ability of future Congresses to update or improve domestic policy. I urge you to ensure the intellectual property chapter advances the global objective of making medicine affordable and accessible for Americans and the millions of people in TPP countries, while protecting the advancement of future policies designed to advance these goals.

Competition in the pharmaceutical industry drives advances in medicines, lowers drug prices and makes medicines accessible for the most vulnerable populations. Policies such as patent linkage, evergreening, and data exclusivity can greatly restrict the ability of generic drugs to enter a market and can prevent market forces from driving innovation and reducing costs. These provisions must be drafted in a manner that is both consistent with U.S. law and existing international standards, particularly the May 2007 New Trade Policy. They must also be crafted with enough flexibility to allow TPP countries to implement policies intended to guarantee access to medicines.

Patent linkage policies have a significant impact on the availability and affordability of medicine because they dictate the ability of generic drugs to enter the market. The U.S. has a patent linkage system that covers some patents for small molecule drugs, but it importantly includes provisions that provide incentives to generic companies to enter the market. I am concerned that the TPP agreement will require linkage for all patents and could go beyond U.S. law. To be consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and our May 2007 New Trade Policy, TPP should permit patent linkage but not mandate it. In addition, any patent linkage provisions must permit the inclusion of safeguards for competition by providing opportunities to challenge the validity or applicability of a patent.

It is crucial that the TPP agreement include a strong standard for the scope of products that can be patented to prevent evergreening. I am particularly concerned that the agreement will include a very broad scope of patentability, including plants and animals, as well as diagnostic,

therapeutic, and surgical methods, and will mandate the granting of secondary patents. The TPP should not require patents to be issued on new forms, uses, or methods for a product if the product's effectiveness and basic makeup remain unchanged. The agreement must also include sufficient flexibility to accommodate future changes to patent standards in the U.S. or any TPP countries. Absent these important limitations on patentability and room for policy changes, the agreement will sanction the indefinite extension of patent protection and create additional monopolies in the drug market. As a result, drug costs will remain high, and drug availability will be limited.

Current U.S. law provides for 12 years of market exclusivity for biologics and five years for small molecules, but no other TPP country has an equivalent policy. In fact, some of the TPP countries provide zero years of data exclusivity for both biologics and small molecules. The agreement must accommodate the market exclusivity policies of all TPP countries, regardless of development level or market size. Imposing existing U.S. biologic market exclusivity requirements on other countries would not only be inconsistent with past free trade agreements, but also would severely limit the introduction of biosimilars in TPP countries. In addition, it could impede Congress' ability to revise U.S. market exclusivity for biologics to seven years, as proposed by President Obama in the past five budget proposals. I ask you to ensure TPP's provisions on market exclusivity reflect the May 2007 New Trade Policy to achieve the appropriate balance between intellectual property protection and access to medicines.

The TPP should not undermine current or future U.S. law and should not require our trading partners to establish new intellectual property regimes that would undermine their public health objectives. Patent linkage, evergreening, and market exclusivity provisions must be crafted carefully to ensure consistency with TRIPS, the May 2007 New Trade Policy, and U.S. law. If the agreement includes intellectual property protections that go beyond existing international standards, it will have permanent ramifications for drug costs in the United States. It will also reverse decades-old international agreements and establish a new global standard of generic drug restrictions. I urge you to ensure the TPP agreement does not include overly restrictive patent protections and instead guarantees patients in all TPP countries will have access to affordable medicines.

Sincerely,

Sherrod Brown

Sherrod Brown
United States Senator